IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

10x GENOMICS, INC.,	)	
	)	
Plaintiff,	)	
	)	C.A. No. 19-862-CFC-SRF
v.	)	
	)	**FILED UNDER SEAL**
CELSEE, INC.,	)	
	)	
Defendant.	)	
	)	

CELSEE, INC.'S MEMORANDUM IN SUPPORT OF ITS FIRST MOTION FOR SUMMARY JUDGMENT (INVALIDITY OF THE HINDSON PATENTS UNDER 35 U.S.C. §112)

Dated: February 5, 2021

Brian E. Farnan (Bar No. 4089)
Michael J. Farnan (Bar No. 5165)
FARNAN LLP
919 N. Market St., 12th Floor
Wilmington, DE 19801
Tel: (302) 777-0300
Fax: (302) 777-0301
bfarnan@farnanlaw.com
mfarnan@farnanlaw.com

Attorneys for Defendant

Of Counsel:

Barbara A. Fiacco
Jeremy A. Younkin
Brendan Jones
Emma S. Winer
Urszula Nowak
Elizabeth Hudson
FOLEY HOAG LLP
Seaport West
155 Seaport Boulevard
Boston, MA 02210
(617) 832-1000
bfiacco@foleyhoag.com
jyounkin@foleyhoag.com
bjones@foleyhoag.com
ewiner@foleyhoag.com
unowak@foleyhoag.com
ehudson@foleyhoag.com

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Celsee submits this Memorandum in support of its First Motion for Summary Judgment of Invalidity of all claims of the "Hindson Patents" asserted by 10x: U.S. Patent Nos. 10,273,541 ("'541") claims 37 and 49; and 10,400,280 ("'280"), claims 1-2 and 30-31.

SUMMARY OF ARGUMENT

Under 35 U.S.C. §112, a patent's specification must describe and enable the invention as broadly as it is claimed, to demonstrate that the inventors actually possessed the claimed subject matter when they applied for their patent and enabled others skilled in the art to practice the full scope of the invention without undue experimentation as of the date the patent application was filed.

The asserted claims of the Hindson Patents cover methods of processing mRNA by partitioning individual cells and barcoded beads in at least 1,000 individual wells of a microwell array. Although the claims encompass microwell-based systems, the common specification concerns ***droplet-based systems***. Tellingly, 10x does not rely on this specification for §112 support. SF1-1; SF1-2.

Instead, 10x cites the '223 Provisional, one of numerous applications to which the Hindson Patents claim priority. The '223 Provisional, filed in March 2013, bears little resemblance to the common specification, not filed until August 2018. SF1-3.

The '223 Provisional is focused on sequencing applications where barcodes are added to short fragments of DNA "to identify the origin of a sequence and, for example, to assemble a larger sequence from sequenced fragments," Ex.C[223], [0061].

The Provisional does not convey possession of the claimed methods of processing mRNA from single cells by partitioning the single cells and barcoded beads. Nor does the Provisional enable the full scope of the asserted claims, which include partitioning beads and cells in an open-ended number of microwells.

The undisputed record of 10x's own work supports these conclusions. 10x [redacted] until ***March 2015***—two years after it filed the Provisional.

BACKGROUND[1]

I. THE ASSERTED CLAIMS

Each asserted claim requires the "partitioning" of single cells with single beads comprising nucleic acid barcode molecules, followed by the release of mRNA from the partitioned cells and the use of reverse transcription to generate barcoded cDNA. SF1-5.

[1] This background is for the Court's convenience. For the facts material to this Motion, see accompanying Statement of Facts ("SF1"). Citations to exhibits ("Ex.") refer to the exhibits attached thereto.

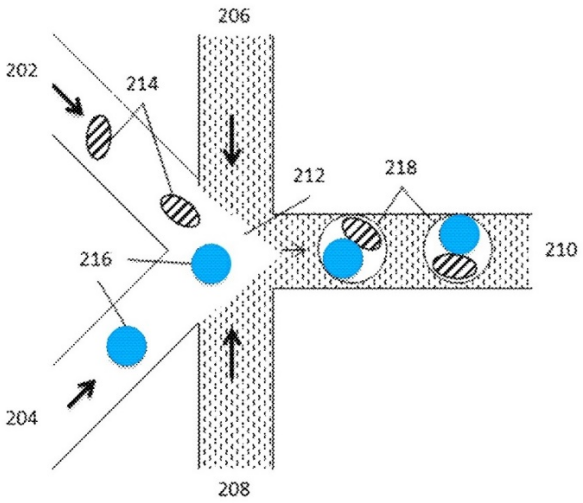
The asserted '541 claims require that single cells and single beads be partitioned in wells of a "microwell array." SF1-6. Independent claim 49 requires that the array comprises "1,000 occupied wells," each with a single cell and a single bead; independent claim 1, from which asserted claim 37 depends, places no limit on the number of occupied wells. Other dependent claims show that the independent claims cover the partitioning of tens of thousands of cells (claims 12, 57) and hundreds of thousands of beads (claim 42) in microwell arrays containing at least one million wells (claims 28, 45, 72).

The asserted '280 claims require a "system" comprising "1,000 occupied partitions" that can be, *inter alia*, wells or droplets, each with a single cell and a single bead. SF1-7.

In short, all of the asserted claims encompass a "microwell array" or "system" with at least 1,000, and up to millions and more occupied wells having a single cell and a single bead.

II. HINDSON PATENT SPECIFICATION

The specification differentiates between partitions that are containers or vessels (such as microwells) and partitions that are "flowable within fluid streams," such as droplet-based partitions, focusing on the latter. SF1-8. The specification's Figure 2, (below, color added) depicts a droplet based-system.



In this system, an aqueous stream carries cells (214) through a channel (202). Ex.A[541], 18:63-65. Another aqueous stream carries beads (216, shaded blue) through a second channel (204). *Id*., 19:1-3. A "partitioning fluid" is introduced through two other channel segments (206, 208). *Id*., 19:3-6. At the channel junction (212), the streams carrying the cells and the beads are combined and "partitioned" into droplets (218) that include a single cell and a single bead in an individual droplet (or "partition"). *Id*., 18:42-46.

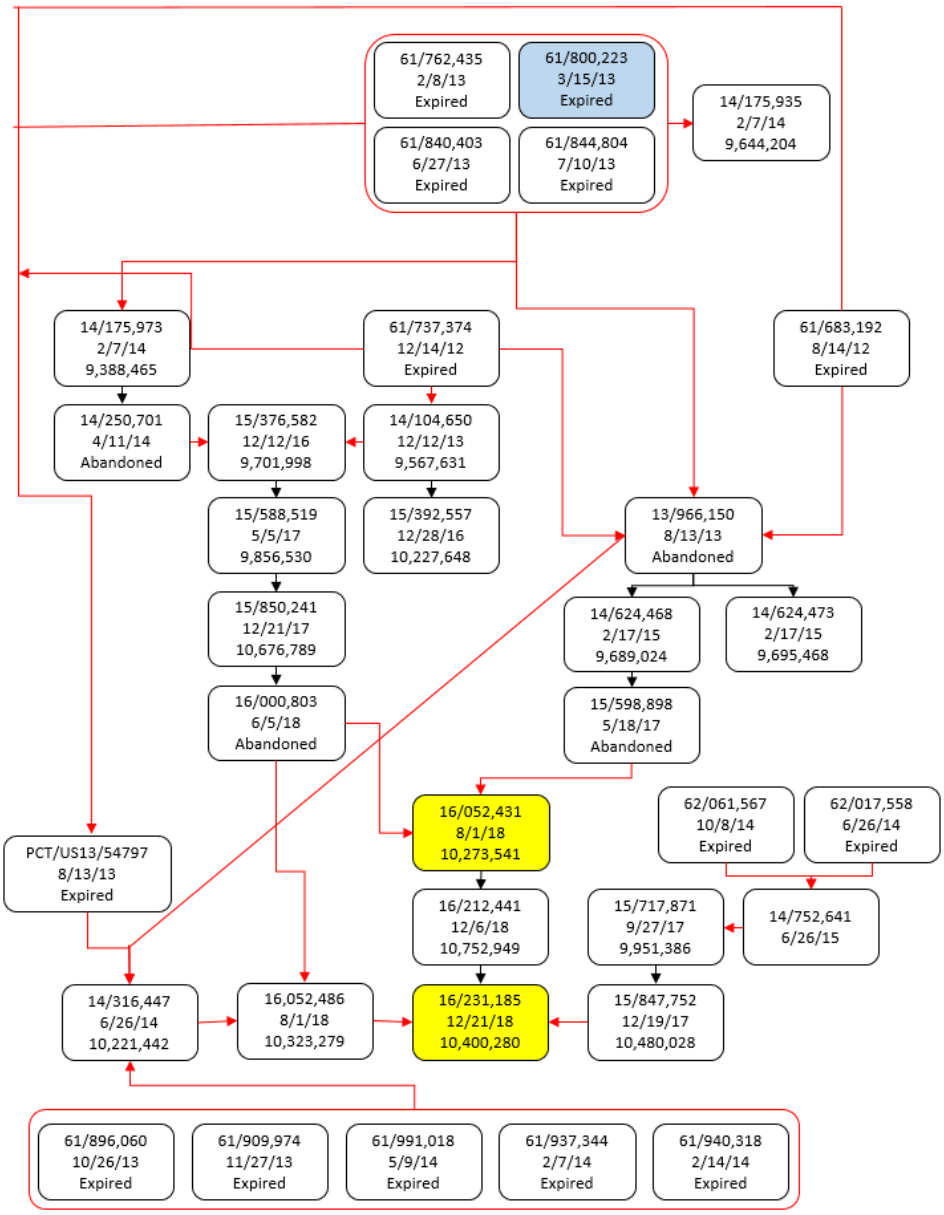
The specification never uses the term "microwell array," nor do any of its 17 figures or 4 examples describe partitioning into a microwell array, let alone one that comprises 1,000 or more occupied wells. SF1-9 to SF1-11. All of the specification's figures, examples, and virtually all its text describe droplet-based systems.

III. '223 PROVISIONAL

As §112 support, 10x relies not on the common specification but on the disclosures in a March 2013 provisional application, Serial No. 61/800,223 ("'223 Provisional"). SF1-2.

A. Hindson Patent Priority Claim

The '223 Provisional (blue highlighted) is part of a convoluted web of provisional applications, continuations, and continuations-in-part ("CIPs") to which the Hindson Patents claim priority, depicted below (continuation applications indicated with black arrows; CIPs indicated with red arrows).



The 2018 application that led to issuance of the ’541 Patent (yellow highlighted) is a continuation-in-part of Application Nos. 16/000,803 and 15/598,898, both of which trace their ancestry through multiple continuations and CIPs back to the four provisional applications shown at the top, including the ’223 Provisional.

The ’280 Patent (yellow highlighted) is a continuation of Application No. 16/212,441, which is a continuation of the ’541 Patent. As a result of this highly complicated and unusual prosecution strategy, the common specification of the ’541 and ’280 Patents—first filed as a CIP in August 2018—was a ***completely new application***. As a CIP, it adds new matter but, contrary to PTO practice, does not “repeat some substantial portion or all of the earlier non provisional application.” MPEP 201.08. Comparison of the 2018 specification and the ’223 Provisional shows that the two applications bear little resemblance. *See* SF1-3.

B. ’223 Provisional Disclosure

The Provisional, titled “Polynucleotide Barcode Generation,” is directed to methods of generating barcodes and to the use of such barcodes in next-generation DNA sequencing applications. *E.g.*, Ex.C[223], [0050]. The next-generation sequencing methods available in March 2013 allowed for sequencing of only short stretches of DNA. To address the problems associated with very short sequence information, the Provisional describes methods for generating longer sequencing reads by barcoding fragments originating from a long polynucleotide molecule with a common barcode. Ex.C[223], [0061].

The ’223 Provisional refers to microwells as one of a laundry list of partitions that can be used when fragmenting DNA. Ex.C[223], [0099-00100] (“a well, a microwell, a hole, a droplet (e.g., a droplet in an emulsion), a continuous

phase of an emulsion, a test tube, a spot, a capsule, a surface of a bead" can be contained within another partition). The Provisional includes only three paragraphs referring to a method for analyzing gene expression— none of which describes a method of partitioning single cells and single beads during the analysis. Ex.C[223], [0194-0196].

ARGUMENT

I. THE ASSERTED CLAIMS ARE INVALID FOR LACK OF WRITTEN DESCRIPTION.

The purpose of §112's written description requirement is two-fold. First, it serves as a quid pro quo "in which the public is given 'meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.'" *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 920, 922 (Fed. Cir. 2004). Second, it "operates as a timing mechanism to ensure fair play in the presentation of claims after the original filing date and to guard against manipulation of that process by the patent applicant." *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1306 (Fed. Cir. 2008); *see also Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1561 (Fed Cir. 1991)("[a]dequate description of the invention guards against the inventor's overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation").

To satisfy written description, the specification must "clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *Ariad Pharms., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). In other words, the specification itself must show that "the inventor actually invented the invention claimed" by "reasonably convey[ing] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.* The written description does not concern what a person of ordinary skill could do, but rather what the inventors themselves ***did*** do. The specification must describe the invention as broadly as it is claimed, to demonstrate that the inventors actually invented the full scope of the claimed invention by the time they filed the application. *See Ariad*, 598 F.3d at 1351-52.

Summary judgment of invalidity for lack of written description is appropriate where the fact-finder could not reasonably find the claimed inventions are adequately disclosed in the specification. *Atl. Research Mktg. Sys., Inc. v. Troy*, 659 F.3d 1345, 1353 (Fed. Cir. 2011); *ICU Med., Inc. v. Alaris Med. Sys.*, 558 F.3d 1368, 1377 (Fed. Cir. 2009); *Univ. of Rochester*, 358 F.3d at 917.

A. The specification does not demonstrate that the inventors possessed the claimed methods.

The Hindson Patent specification, first filed in August 2018, does not describe a complete method for processing mRNA from single cells using a microwell array. None of the specification's 17 figures or four examples employs a

microwell array. *Boston Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1364 (Fed. Cir. 2011) ("The lack of any disclosure of examples may be considered when determining whether the claimed invention adequately described."). Nowhere does the specification use the term "microwell array." SF1-9.

Section II of the "Detailed Description" ("Compartmentalization and Characterization of Cells") discusses the partitioning of cells, but uses the term microwells only once, distinguishing partitions that are containers or vessels (such as a microwell) from partitions that are "flowable within fluid streams." Ex.A[541], 9:28-31. The remainder of Section II's discussion of partitioning focuses on droplet-based partitioning. SF1-12.

The 2018 specification does not demonstrate to a POSA that the 10x inventors possessed the microwell array-based single-cell methods covered by the asserted claims. 10x does not dispute this, but instead argues that the '223 Provisional provides written description support. SF1-2.

B. 10x's attempt to rely on the '223 Provisional is wrong as a matter of law.

10x's attempt to rely on the '223 Provisional for support violates the requirements of §112. 10x's argument also contravenes the policy underlying §112. It would allow an applicant to hide relevant disclosures in a complex maze of patent applications, like the one depicted above. Such manipulation of USPTO rules should be rejected.

The 2018 specification purports to incorporate by reference the '223 Provisional in the convoluted "Cross Reference to Related Applications" section, which contains boilerplate language that each of ***twenty-two*** patent applications are "entirely incorporated herein by reference for all purposes." *See* SF1-4. This does not identify ***with detailed particularit***y what ***specific*** material from the Provisional it incorporates by reference, as required by Federal Circuit precedent. *See Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000).

The Court should determine, as a matter of law, that 10x cannot rely on the '223 Provisional to provide written description support for the asserted claims.

C. The '223 Provisional does not provide written description for the asserted claims.

Even if 10x could rely on the Provisional, it does not provide written description for the asserted claims for multiple reasons.

1. The '223 Provisional does not demonstrate that the inventors had possession of the inventions as a whole.

In assessing written description, "each claim [must be taken] as an integrated whole rather than as a collection of independent limitations." *Novozymes A/S v. Dupont Nutrition BioSciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013).

The '223 Provisional fails to describe a method of processing mRNA from single cells by performing the specific combination of steps recited in the asserted

claims. SF1-13. The Provisional focuses on methods of sequencing where barcodes are added to short fragments of DNA "to identify the origin of a sequence and, for example, to assemble a larger sequence from sequenced fragments." Ex.C[223], [0050], [0061]. These methods are not claimed in the Hindson Patents. At his deposition, 10x's expert could not identify ***any*** portion of the Provisional providing a narrative description of the specific methods recited in the asserted claims. SF1-14.

Only three paragraphs [0194-0196] of the Provisional refer to assays for gene expression analysis, and none include the steps required by the asserted claims: there is no disclosure of beads; no disclosure of co-partitioning single cells with beads[2]; no disclosure of beads comprising barcode molecules; no disclosure of attaching mRNA to such barcode molecules; no disclosure of using reverse transcription to yield barcoded cDNA molecules;[3] no disclosure of performing the

[2] The only disclosure in the Provisional referencing beads within wells is in an unconnected section disclosing a long laundry list of partitions that can be placed within other partitions. 10x's expert acknowledged that this disclosure placed no emphasis on this particular combination of partitions. Ex.H. 229:25-230:25. *See Novozymes*, 723 F.3d at 1349. No reasonable fact-finder could find that the Provisional demonstrates possession of methods of partitioning a single cell and a single bead (attached to a barcode or not).

[3] 10x identified only one paragraph [00195] to support this step which states "[r]everse transcription of mRNA may be performed in a partition, or outside of such a partition." This does not describe the use of reverse transcription to generate barcoded cDNA as required by the asserted claims. Instead, the cited disclosure

assay on cancer cells (’541 claim 37); no disclosure of the performance of a nucleic acid amplification reaction (’541 claim 49); no disclosure of “an identification barcode sequence configured to quantify mRNA molecules” or its use (all ’280 claims); no disclosure of a partition containing an antibody (’280 claim 30); and no disclosure of a microwell array comprising an inlet port (’280 claim 31). SF1-15 to SF1-25.

10x makes futile attempts to identify some of the above claim elements in disparate, unconnected sections of the Provisional, but it is black-letter law that written description support requires more than an “amalgam of disclosures plucked selectively from the [specification].” *Novozymes*, 723 F.3d at 1349; *see also Lockwood* v. *Am. Airlines*, 107 F.3d 1565 at 1572 (Fed. Cir. 1997); *Purdue Pharma L.P. v. Recro Tech., LLC*, 694 F. App’x 794, 797 (Fed. Cir. 2017) (the written description test is not whether “a person of skill in the art would isolate and combine aspects from various embodiments in the specifications . . . to obtain the claimed invention”).

In sum, no reasonable fact-finder could conclude that the ’223 Provisional suggests, much less “reasonably conveys” that the 10x inventors “actually

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states that “the ***methods of the invention*** may be used to ***fragment and barcode*** the polynucleotides of the cell for sequencing.”

invented" a method of processing mRNA from single cells by performing the specific combination of steps recited in the asserted claims.

2. The '223 Provisional Does Not Disclose a System Comprising 1,000 Occupied Partitions.

The Provisional also fails to disclose the claimed threshold level of occupied partitions or wells, including: a microwell array comprising 1,000 occupied wells, each well comprising a single cell and a single bead ('541 claim 49); a system comprising 1,000 occupied partitions, each partition comprising a single cell and a single bead ('280 claims 1, 30, 31); and the system of claim 1 comprising 5,000 occupied partitions ('280 claim 2). Indeed, the Provisional does not disclose ***any*** threshold level of occupied partitions or wells. Ex.G ¶¶143, 238, 416, 433. SF1-26.

10x's expert opines that these thresholds are met because "the inventors describe that the number of partitions can be up to 50,000 partitions, and that the ratio of the number of species to the number of partitions may range from about 0.1-1000." Ex.I ¶¶672, 688. However, the disclosure cited to support "that the number of partitions can be up to 50,000" simply states that "[a]ny partition described herein ***may comprise multiple partitions***. For example, ***a partition may comprise… 50000 partitions***." Ex.C[223], [0101](emphasis added). In other words, the Provisional states that a single partition can include 50,000 other partitions (*e.g.*, a single well can contain 50,000 beads), not that a single-cell system can include 50,000 partitions, each with a cell and a bead.

The 1,000-occupied-microwells, 1,000-occupied-partitions, and 5,000-occupied-partitions limitations cannot reasonably be derived from the Provisional's disclosure. *General Hosp. Corp. v. Sienna Biopharma., Inc*., 888 F3.d 1368, 1372 (Fed. Cir. 2018) ("disclosure of a broad range of values does not by itself provide written description for a particular value within that range"). Indeed, 10x's expert does not even attempt to explain how the cited disclosure would convey possession of a system comprising 1,000 (or 5,000) occupied partitions, each containing a single cell and a single bead. *See, e.g., Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1326 (Fed. Cir. 2000) ("[O]ne cannot disclose a forest in the original application, and then later pick a tree out of the forest and say here is my invention.").

A fact-finder therefore could not reasonably conclude that the '223 Provisional conveys possession of a system or microwell array that comprises 1,000 (or 5,000) wells occupied by a single well and a single bead. The '541 claim 49 and '280 claims 1, 2, 30, and 31 lack written description.

D. Inventor Testimony Confirms that They Did Not Possess the Claimed Methods

While inventor testimony is unnecessary to show that claims lack adequate description, testimony of the named inventors and 10x's own documents reinforce the conclusion that the inventors did not invent a method for processing mRNA

from single cells using microwell arrays to partition single cells with single beads, let alone those comprising 1,000 or more occupied wells.

10x was formed in the summer of 2012 with the aim of [redacted]. *See* Ex.M at 63. By early 2013, 10x [redacted], so 10x [redacted]. Ex.N at 162:5-19; 195:23-25; 203:20-206:5.

As of August 2014—over a year after the 10x filed the Provisional—10x [redacted]. Ex.M at 96-97. 10x [redacted] in September 2014. Ex.P. ***At no time did 10x scientists*** [redacted]. Ex.M at 138.

10x inventors' testimony as well as internal documents confirm what the March 2013 Provisional and the later-filed 2018 specification demonstrate: that the inventors [redacted], either in 2013 or 2018. *See Wang Labs., Inc. v. America Online, Inc.*, 197 F.3d 1377, 1382-83 (Fed. Cir. 1999)(inventors' inability to implement a particular type of system was evidence that such system was not

described in specification); *Boston Sci. Corp. v. Johnson & Johnson*, 679 F.Supp.2d 539, 555 (D. Del. 2010).

II. THE ASSERTED CLAIMS ARE INVALID FOR LACK OF ENABLEMENT.

The enablement requirement "serves the dual function in the patent system of ensuring adequate disclosure of the claimed invention and of preventing claims broader than the disclosed invention." *MagSil Corp. v. Hitachi Glob. Storage Techs., Inc.*, 687 F.3d 1377, 1380-81 (Fed. Cir. 2012). "To be enabling, the specification of a patent must teach those skilled in the art how to make and use ***the full scope*** of the claimed invention without undue experimentation" as of the patent's effective filing date. *Id*. at 1380 (emphasis added). Enablement is a question of law based on underlying factual findings. *Id.*

A method claim reciting an open-ended range lacks enablement if the specification does not teach one of ordinary skill to make and use the claimed method across the full scope of the range. *Id*. at 1384.

A. The asserted claims encompass an unbounded number of occupied wells or partitions.

Each asserted claim includes an open-ended range of occupied microwells or "partitions." The '280 claims require a "system ***comprising*** 1,000 occupied partitions," *e.g.*, wells, each with a single cell and a single bead. Similarly, '541 claim 49 requires single cells and single beads to be partitioned in a "microwell

array" that "***comprises*** 1,000 occupied wells." Thus, the '280 claims and '541 claim 49 require ***at least*** 1,000 occupied wells and encompass hundreds of thousands, millions, or even more occupied wells. The use of "comprising" in these claims creates an open-ended range which must be enabled across its entirety. *See, e.g.*, *Promega Corp. v. Life Techs. Corp.*, 773 F.3d 1338, 1350 (Fed. Cir. 2014).

Claim 37 of the '541 Patent, which depends from claim 1, requires partitioning of cells and beads "in a microwell array ***comprising*** a plurality of wells" but places ***no upper limit*** on the number of cells, beads or wells used in the method. The unbounded range is underscored by dependent claims adding further limitations on the method of claim 1. *See* 35 USC §112(d); claims 12 (partitioning at least 10,000 cells), 42 (partitioning at least 100,000 beads), 45 (microarray includes at least 1,000,000 wells).

B. The 2018 specification does not enable the full scope of the claimed ranges.

In Celsee's Invalidity Contentions and expert report, Celsee contended that the 2018 specification does not enable the full scope of the claims: it provides no working examples of a complete method for processing mRNA from single cells using a microwell array nor does it provide any guidance with respect to performance of the claimed methods. *See* Ex.O; Ex.G ¶¶439-441. 10x's contention responses identified only the '223 Provisional as providing enablement

support and 10x offered no expert opinion that the 2018 specification enables the claims. 10x thus accepts that the 2018 specification does not itself enable the asserted claims. SF1-27.

C. The '223 Provisional does not enable the full scope of the claimed ranges.

10x improperly contends that the Provisional provides an enabling disclosure. It does not. The Provisional provides no working examples and no guidance to address the extensive challenges associated with scaling-up single-cell analysis systems to practice the full scope of the claims. Celsee's experts opined that, in view of the Provisional's lack of relevant disclosure, a POSA in March 2013 would not be able to perform the full scope of the claimed methods without undue experimentation. Ex.J ¶¶59-60; Ex.G, ¶¶438-460. They further opined that the state of the art was such that skilled artisans were only capable of performing relatively small-scale single-cell RNA expression assays in microwells, i.e., less than about 5,000 wells occupied with a single bead and a single cell. Ex.J, ¶¶61-64.

10x's expert opinion of Dr. Juan Santiago does not create a triable issue.[4] First, Dr. Santiago misunderstands the scope of the claims, incorrectly believing

[4] 10x expert Dr. Quackenbush offers a conclusory opinion, based on Dr. Santiago's opinion, that the asserted claims are enabled "to the limits of what was permitted by technology existing in 2013" without further explanation of the limits. Ex.I

that the "largest scale requirements in any claim of the '541 or '280 patent is 10,000 occupied wells ('541 claim 57, '280 claim 3) and 1,000,000 total wells ('541 claim 28)." SF1-29. As noted above, the open-ended "comprising" claims encompass ***more than*** 10,000 occupied wells ***and more than*** 1,000,000 total wells.

Dr. Santiago concedes, however, that the Provisional provides no working examples of the claimed methods of single-cell analysis using microwell arrays; instead, he relies entirely on the assertion that the state of the art in liquid-handling technology as of March 2013 enables the claimed methods ***up to*** 10,000 occupied wells and 1,000,000 total wells. SF1-28; SF1-30. These limits do not represent the full scope of the issued claims, as he readily admits. *Id.* His opinion is an outright admission of non-enablement.

Dr. Santiago testified that, although he believes there is a practical upper limit on '280 claim 1, he testified that he does not know the upper limit, believes it is a "difficult question," and "would say it's greater than 10,000 as of 2013…." SF1-31; SF1-32. He further admitted that he did not undertake to determine the upper limit of '541 claim 49 in forming his enablement opinions. SF1-33. Finally, Dr. Santiago admitted that the upper limit of what is practical has changed over time: "there have been advances that would help increase the upper limit from

¶¶714-715. Dr. Quackenbush's wholly conclusory opinion does not create a dispute of fact.

2013 to today." SF1-34. In other words, 10x has no evidence of what the upper limit would be or that skilled artisans as of the priority date would know what it is.

In these circumstances, the claims are not enabled. *See Magsil*, 687 F.3d at 1381 ("a patentee chooses broad claim language at the peril of losing any claim that cannot be enabled across its full scope of coverage.").

Dated: February 5, 2021

Respectfully submitted,

FARNAN LLP

/s/ Brian E. Farnan
Brian E. Farnan (Bar No. 4089)
Michael J. Farnan (Bar No. 5165)
919 N. Market St., 12th Floor
Wilmington, DE 19801
(302) 777-0300
(302) 777-0301 (Fax)
bfarnan@farnanlaw.com
mfarnan@farnanlaw.com

Attorneys for Defendant

Of Counsel:

Barbara A. Fiacco
bfiacco@foleyhoag.com
Jeremy A. Younkin
jyounkin@foleyhoag.com
Brendan T. Jones
bjones@foleyhoag.com
Emma S. Winer
ewiner@foleyhoag.com
Urszula Nowak
unowak@foleyhoag.com
Elizabeth Hudson
ehudson@foleyhoag.com
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, Massachusetts 02210
(617) 832-1000

CERTIFICATION OF COMPLIANCE

The foregoing document complies with the type-volume limitation of this Court's March 2, 2020 form Scheduling Order For All Cases where Infringement is Alleged. The text of this brief, including footnotes, was prepared in Times New Roman, 14 point. According to the word processing system used to prepare it, the brief contains 4,150 words, excluding the case caption, signature block, table of contents and table of authorities.

/s/ Brian E. Farnan
Brian E. Farnan (Bar No. 4089)

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